

**PATENT APPLICATION**  
**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of

Docket No: Q91867

Francesco MAKOVEC, et al.

Appln. No.: 10/562,013

Group Art Unit: 1621

Confirmation No.: 2981

Examiner: Lalitha Nagubandi

Filed: December 23, 2005

For: METHOD FOR THE PREPARATION OF CRYSTALLINE DEXLOXIGLUMIDE AND  
PRODUCTS OBTAINED

**DECLARATION UNDER 37 C.F.R. § 1.132**

**MAIL STOP AMENDMENT**

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

I, Dr. Francesco Makovec, am a co-inventor of the presently claimed subject matter in  
U.S. Patent Application No. 10/562,013.

I declare further that I am familiar with the rejection of claims 1-14 as being unpatentable  
for obviousness over U.S. Patent No. 5,130,474 ("Makovec") in combination with U.S. Patent  
No. 5,314,506 ("Midler"), as set forth in the Office Action mailed August 3, 2007.

In support of the patentability of the present claims, I conducted the following  
comparative experiment.

For comparison purposes, the following analytical results relating to lot G3756-A were  
obtained according to the process of Working Example 1 of the present application *without* the

addition of the seeding material. In the comparative example, the average particle size ( $D_{50}$ ) for the obtained product was 15.025  $\mu\text{m}$ , and the span index was 3.845.

I submit that these results are clearly different from those obtained by the presently claimed method, wherein the mean size measurement ( $D_{50}$ ) was 97.357 and the span index was 1.608. See the last full paragraph on page 8 of the present specification. Further, I submit that the superior results obtained by the presently claimed method would have been unexpected to a person of ordinary skill in the art at the time of the invention.

I declare still further that all statements made herein, including in all attachments hereto, of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: \_\_\_\_\_

\_\_\_\_\_  
Dr. Francesco Makovec